

CLAIMS

What is claimed is:

1. A unit dose composition for inducing angiogenesis in a
5 human, comprising about .008 mg to about 7.2 mg of FGF-2 or an
angiogenically active fragment or mutein thereof in a pharmaceutically acceptable
carrier.
- 2 The unit dose composition of claim 1, comprising 0.3 mg
10 to 3.5 mg of FGF-2, or an angiogenically active fragment or mutein thereof.
3. The unit dose composition of claim 1, wherein said FGF-2
has the amino acid sequence of SEQ ID NO: 2.
- 15 4. The unit dose composition of claim 3, comprising 0.3 mg
to 3.5 mg of an FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or
mutein thereof in a pharmaceutically acceptable carrier.
5. The unit dose composition of claim 3, comprising about
20 .008 mg to about 7.2 mg of said angiogenically active mutein of said FGF-2 of
SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

6. The unit dose composition of claim 5, comprising 0.3 mg to 3.5 mg of said angiogenically active mutein of said FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

5 7. The unit dose composition of claim 3, comprising about .008 mg to about 7.2 mg of said angiogenically active fragment of said FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

10 8. The unit dose composition of claim 7, comprising 0.3 mg to 3.5 mg of said angiogenically active fragment of said FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

15 9. The unit dose composition of claim 3, comprising about .008 mg to about 7.2 mg of FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier in a pharmaceutically acceptable carrier.

20 10. A method for treating a human patient for coronary artery disease comprising, administering a safe and therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 µg/kg to 48 µg/kg of patient weight.

11. The method of claim 10, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

12. The method of claim 11, further comprising the step of
5 administering to said human patient about 10 U/kg to 80 U/kg of heparin within about 0 to 30 minutes prior to administering said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof.

13. The method of claim 12, wherein said therapeutically
10 effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is administered to one or more coronary vessels.

14. The method of claim 13, wherein said therapeutically
15 effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is about 24 µg/kg to 48 µg/kg.

15. The method of claim 12 wherein said therapeutically
effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said
20 angiogenically active fragment or mutein thereof is administered to a peripheral vein.

16. The method of claim 15, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is about 18 µg/kg to 36 µg/kg.

5 17. A method for treating a human patient for coronary artery disease comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg
10 of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

18. The method of claim 17, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

15 19. The method of claim 18, wherein said single unit dose produces a therapeutic benefit in said human patient that lasts at least four months.

20 20. The method of claim 19, wherein said single unit dose produces a therapeutic benefit in said human patient that lasts 6 months.

21. The method of claim 20, wherein said single unit dose produces a therapeutic benefit of such magnitude and duration in said human

patient such that administration of a second unit dose is not required for about 6 months.

22. The method of claim 20, wherein said unit dose is
5 administered to one or more coronary arteries.

23. The method of claim 20, wherein said unit dose is administered to a peripheral vein.

10 24. The method of claim 20, wherein said unit dose comprises 0.3 mg to 3.5 mg of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof.

15 25. The method of claim 19, further comprising the step of administering 10 U/kg to 80 U/kg of heparin to said patient IV or IC about 0 to 30 minutes prior to administering said unit dose.

20 26. A method for inducing angiogenesis in a heart of a human patient comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

27. The method of claim 26, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

5 28. The method of claim 27 wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts at least four months.

10 29. The method of claim 28, wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts 6 months.

15 30. A method for treating a human patient for a myocardial infarction comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

20 31. The method of claim 30, further comprising the step of administering 10 U/kg to 80 U/kg of heparin to said patient IV or IC about 0 to 30 minutes prior to administering said unit dose.

32. The method of claim 31, wherein FGF-2 has the amino acid sequence of the SEQ ID NO: 2.

33. The method of claim 30, wherein said unit dose is
5 administered to a peripheral vein.

34. The method of claim 30, wherein said unit dose is administered into one or more coronary vessels of said patient.